K053538 Page 1/2

510(k) Summary

General Information

Submitter Information:

OCT 10 2006

CuraPharm, Inc.
10054 Prospect Avenue, Suite F
Santee, CA 92071, USA
619-449-7388
619-449-7453

Point of Contact: Thomas Hnat
Date Summary was prepared: January 10, 2006

Device Name: Phytacare® Alginate Hydrogel, Wound Dressing
Common Name: Hydrogel, Wound Dressing

Legally Marketed Devices to which Substantial Equivalence is Claimed:
The Phytacare® Alginate Hydrogel, Wound Dressing is substantially equivalent to one or more of the following devices.

1. K962218 - CarraGauze® Carrasyn Hydrogel, Wound Dressing, Carrington Laboratories
2. K53450 - Curasol® Gel, Wound Dressing, Healthpoint Medical
3. Unknown - TransiGel® Conformable Gel Dressing, Smith & Nephew United, Inc.
4. K935096 - Biolex Impregnated Wound Dressing, C.R. Bard, Inc.
5. K954738 - DermaGran® Hydrophyllic Wound Dressing, Derma Sciences
6. K942270 - Saf-Gel®, Hydrating Dermal Wound Dressing with Alginate ConvaTec
7. K053538 - Phytacare® Alginate Hydrogel Wound Dressing, PhytaTek Laboratories

Description of Device: There are 2 components of the device. Phytacare® Alginate Hydrogel and the airless pump container. Phytacare® Alginate Hydrogel Wound Dressing contains sodium alginate, whose primary function is to absorb excess wound exudate, providing a moist wound environment to encourage natural healing. Phytacare® Alginate hydrogel also contains moisturizers, thickeners and stabilizers, preservatives, and a fragrance. The Phytacare® Alginate Hydrogel is packaged in 30 or 50 ml polypropylene airless pump containers.

Intended Use of the Device: Phytacare® Alginate Hydrogel Wound Dressing is an Alginate Hydrogel that is indicated for the management of diabetic ulcers, foot ulcers, 1st and 2nd degree burns, pressure ulcers stages I- IV, cuts and abrasions. This intended use is shared by the predicate devices.

Technological Characteristics of the Device: Comparison to the Predicate Device: Phytacare® Alginate Hydrogel Wound Dressing is similar in function, composition, and intended use to the predicate devices, all gel and gel-type wound dressings as described above. Phytacare® Alginate Hydrogel Wound Dressing also contains sodium alginate, whose primary function is to absorb excess wound exudate, providing a moist wound environment to encourage natural healing.

Performance Data: Standard biocompatibility tests including sensitization, cytotoxicity, acute systemic toxicity, and intracutaneous reactivity were performed on the Phytacare® Alginate Hydrogel to establish device safety. The above tests and assays are typically performed for medical devices such as wound dressings. All tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by North America Science Associates, Inc. (NAmSA). The studies indicated that Phytacare® Alginate Hydrogel is safe for its intended use.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2006

CuraPharm, Inc.
% Mr. Thomas Hnat
President
10054 Prospect Avenue, Suite F
Santee, California 92071

Re: K053538
Trade/Device Name: Phytacare Alginate Hydrogel Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 11, 2006
Received: August 15, 2006

Dear Mr. Hnat:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

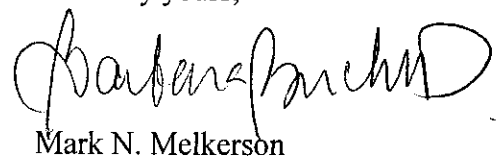
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K053538**

Device Name: **Phytacare Alginate Hydrogel Wound Dressing**

Indications For Use:

The Phytacare Alginate Hydrogel Wound Dressing is indicated for use in the management of 1st and 2nd degree burns, minor cuts and abrasions.

Under the care of a healthcare professional the Phytacare Alginate Hydrogel Wound Dressing is indicated for use in the management of diabetic ulcers, foot ulcers, 1st and 2nd degree burns, pressure ulcers (stages I-IV), cuts and abrasions.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Smith

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053538